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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND
INTERFERENCES

In re Application of: **Rapp, et al.**
Application No.: **10/031,851** Examiner: **CHONG, Yong Soo**
Filed: **May 28, 2002** Docket No.: **HMNZ 2 00021**
For: **USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE
SKIN, MUCOUS MEMBRANES, ORGANS AND TISSUES**

MAIL STOP APPEAL BRIEF — PATENTS
Commissioner for Patents
P.O. Box 1450
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TRANSMITTAL OF APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Dear Sir:

Applicant transmits herewith one (1) originally signed copy of the APPEAL BRIEF UNDER 37 C.F.R. § 41.37 for the above-identified patent application.

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Respectfully submitted,
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December 21, 2006
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Cathryn Terzhek

Date: December 21, 2006



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S) : Rapp, et al.
TITLE : USE OF TOSYLCHLORAMIDE(S)
FOR TREATING DISEASES OF THE
SKIN, MUCOUS MEMBRANES,
ORGANS AND TISSUES
APPLICATION NO. : 10/031,851
FILED : May 28, 2002
CONFIRMATION NO. : 8437
EXAMINER : Chong, Yong Soo
ART UNIT : 1617
LAST OFFICE ACTION : August 15, 2006
ATTORNEY DOCKET NO. : HMNZ 2 00021

APPEAL BRIEF UNDER 37 C.F.R. §41.37

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Dear Sir:

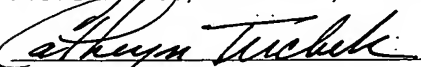
This Appeal Brief is in furtherance of the Notice of Appeal mailed to the U.S. Patent and Trademark Office on November 15, 2006.

The fees required under 37 C.F.R. §41.20(b)(2) and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying Transmittal of Appeal Brief.

Appellant files herewith an Appeal Brief in connection with the above-identified application wherein claims 1-19 were finally rejected in the Final Office Action of August 15, 2006.

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I. REAL PARTY IN INTEREST (37 C.F.R. §41.37(c)(1)(i))

The real parties in interest in this appeal are the inventors named in the caption of this brief (Horst Rapp and Friedbert Heck).

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. §41.37(c)(1)(ii))

Currently, it is believed that there are no other appeals or interferences in process or pending before the U.S. Patent and Trademark Office which the present application bases its priority from, or any cases which base their priority upon the present application, that will directly affect, or will be directly affected by, or will have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS (37 C.F.R. §41.37(c)(1)(iii))

The status of the claims set forth after the Advisory Action mailed July 15, 2005 was, and is, as follows:

Allowed:	none
Rejected Claims:	1-19

The present appeal is directed specifically to claims 1-19.

IV. STATUS OF THE AMENDMENT (37 C.F.R. §41.37(c)(1)(iv))

No amendments have been made that have not been entered by the Examiner.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER (37 C.F.R. §41.37(c)(1)(v))

Independent claim 1 recites a method of treating diseases of the skin selected from psoriasis, neurodermatitis, shingles, aphthae, lip rhagade, stomatitis herpetica, vessels with watery liquid, and diseases of the skin and mucous membrane caused by herpes simplex virae, the method comprising the administration to the area to be treated of tosylchloramide(s), tosylchloramide salt(s), or mixtures thereof. (page 3, line 1 – page 4, line 9; also see examples 5 and 7 generally, pages 11-14).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R.

§41.37(c)(1)(vi))

The Examiner has now rejected claims 1-6, 9-13 and 17 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,317,540 to Wakeman ("Wakeman"). The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over WO91/07876 to Vandavelde ("Vandavelde"). The Examiner also rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over DE4137544 to Harwardt ("Harwardt").

VII. ARGUMENTS (37 C.F.R. §41.37(c)(1)(vii))

A. The Rejection Based on Wakeman

The Examiner has rejected claims 1-6, 9-13 and 17 as being unpatentable over Wakeman. Appellants respectfully traverse.

Wakeman is directed to the use of quaternary ammonium aromatic sulfonamides for disinfection and as bacteriostat agents (col. 3, line 13 – col. 4, line 15). Wakeman neither discloses nor suggests a method for the treatment of the specifically claimed diseases by administering compositions containing tosylchloramide(s), tosylchloramide salt(s), and mixtures thereof. In support of his rejection, the Examiner states that it would have been obvious to use the compositions of Wakeman in the treatment of the presently claimed skin diseases because Wakeman discloses the use of tosylchloramide as a topical antiseptic, antidandruff agent, etc. and that one skilled in the art would reasonably have expected that such compositions would be useful in treating the particular skin diseases.

Appellants respectfully traverse. Wakeman neither discloses nor suggests the use of tosylchloramide compounds in the treatment of the particular skin diseases or even diseases that are remotely similar. The causes of the recited skin diseases are many and varied. Is the Examiner suggesting that Wakeman would render claims drawn to the treatment of ANY skin disease using a tosylchloramide composition obvious? The Appellants hope the Board will appreciate that this type of argument is completely inappropriate and ill-informed.

The fact is that different ailments require different treatments, and unless such ailments are extremely close in both cause and manifestation (which is not the case here), the use of a compound in the treatment of one would not render obvious its use in the treatment of the other.

The useful applications for the reaction products disclosed in Wakeman as mildewproofing, odor preservative, topical antiseptics and disinfection agents, and the like (see column 3, line 39 to column 4, line 15).

The skilled artisan could not expect that a chemical agent useful as disinfectant would be useful as a pharmaceutical for treating diseases of the skin. There are many chemical disinfectants, which do not have appropriate pharmaceutical properties. Furthermore, the skilled artisan could not have received from the overall disclosure of Wakeman any incentive to consider a pharmaceutical activity useful for the treatment of skin diseases using the compounds disclosed therein.

In summary, Wakeman cannot render obvious the subject-matter according to claim 1 of the present invention because the compounds disclosed as microbiologically active compounds are different from tosylchloramide as required in the method according to claim 1 of the present invention. Furthermore, the compounds disclosed in Wakeman are disclosed as microbiologically active disinfectants and there is no hint whatsoever in this document that tosylchloramide could be useful in a method for the treatment of diseases of the skin selected as described in claim 1 of the present invention. Rather, the useful applications for the reaction products disclosed in Wakeman as mildewproofing, odor preservative, topical antiseptics and disinfection agents, and the like (see column 3, line 39 to column 4, line 15).

The main argument of the Examiner, both with respect to Wakeman as well as Vandeveld and Harwardt as well, seems to be that he deems the use of certain compounds as disinfectants as rendering obvious the use of such compounds for treating diseases of the skin. However, it is simply not the case that compounds useful as disinfectants are usually also useful for the treatment of skin diseases. To the contrary, disinfectants are normally not useful for the treatment of skin diseases and are in fact not used for such purposes. This is the case for many

reasons. One of the reasons is simply that disinfectants are normally not able to penetrate the skin and can therefore not attach microorganisms which are within or under the skin.

The Board will appreciate that disinfectants one hand and compounds for treatment of diseases, including antibiotics and other compounds, are entirely different types of compounds and have been classified in different classes by the patent office. It is quite rare that compounds useful as disinfectants can successfully be used as pharmaceutical compounds for the treatment of skin diseases.

A recent case decided by the Federal Circuit is illustrative of the Appellants position. In *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, (Fed. Cir. 2005). The Court held that claims for a method of treating sunburned skin were not inherently anticipated by prior art directed to cosmetic compositions containing the same exact same compounds for topical application, since the disclosed use of the prior art lotion did not suggest application of the lotion to skin sunburn.

In making this holding, the Court dismissed the district court's holding and the dissent by stating,

Like the district court, the dissent seems to ignore, or at least dismiss as 'not substantial,' the distinction between Dr. Perricone's claimed method and Pereira's disclosed method. Thus, the dissent characterizes both methods the same way: 'Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin.' Unfortunately, the dissent can make that statement only by dismissing the explicit language of Dr. Perricone's claimed method: 'applying to the skin sunburn.' '693 patent, claim 1. Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn.

In the present case, the prior art is even more dissimilar in that it does not even disclose or suggest topical skin application of the compounds, let alone application to skin for treatment of diseases.

For at least the above reasons, Applicants respectfully request withdrawal of this rejection.

B. The Rejection based on Vandeveld

The Examiner has rejected claims 1-19 as being unpatentable over Vandeveld. Appellants respectfully traverse.

Vandeveldel is directed to an agent which acts against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV), on and/or in inanimate objects, said agent consisting of a chlorinated organic compound which stably and lastingly releases chlorine when in solution, a composition for disinfecting inanimate objects containing at least one of the above-mentioned agents, and the use of such an agent or composition to disinfect inanimate objects, are described, as well as the use of at least one chlorinated organic compound which stably and lastingly released available chlorine when in solution in order to prepare a therapeutic composition which acts against said retrovirus group viruses (see abstract).

Consequently, Vandeveldel is explicitly restricted to the use of chlorinated organic compounds, which stably and lastingly release chlorine, against retrovirus group viruses, in particular Human Immunodeficiency Virus (HIV). In contrast, the use against retrovirus diseases is specifically disclaimed in the subject-matter of claim 1 according to the present invention. Despite the Examiner's assertion to the contrary, the fact that the compounds of Vandeveldel are useful against retroviruses does not suggest that they would be useful in the treatment of the skin conditions recited in claim 1. Many, many compounds are used to specifically treat singular conditions. There is simply no suggestion for using the compounds of Vandeveldel in the treatment of the recited diseases. Thus, the subject-matter of claim 1 according to the present invention is not rendered obvious by the disclosure of Vandeveldel.

Further, Vandeveldel is clearly directed to the disinfection of inanimate objects (see abstract and claim 1). The specific teaching of Vandeveldel is the disinfection of inanimate objects against retrovirus group viruses (in particular Human Immunodeficiency Virus [HIV]). Therefore the skilled artisan would not have received any incentives from the disclosure of Vandeveldel to consider the use of tosylchloramide and/or tosylchloramide salts for the manufacture of medicaments to treat diseases of the skin, mucous membranes, organs or tissues, except for treatment of retroviral diseases and disinfection. That is, just because a compound is useful for the disinfection of inanimate objects does not necessarily mean that the compound would be useful could even be used on the skin for treatment of the

diseases thereof. Consequently, the subject-matter according to claim 1 of the present invention is also inventive over Vandavelde.

C. The Rejection Based on Harwardt

The Examiner rejected claims 1-19 as unpatentable over Harwardt. Appellants respectfully disagree.

DE 41 37 544 (Harwardt) is directed to an antimicrobial combination on the basis of compounds, which are able to split off oxygen. The basis of Harwardt is that a special combination of chemical compounds as disinfectant is obtained which is highly active as a disinfectant while at the same time is well tolerated on the skin. Harwardt does not disclose a method of treating diseases of the skin. There are many compounds suitable as disinfectants which at the same time are not useful in methods of treating diseases of the skin and therefore, the skilled artisan when reading the disclosure of Harwardt would not receive any incentive to think along these lines. Therefore, the subject-matter of the claims of the present invention are non-obvious over Harwardt.

CONCLUSION

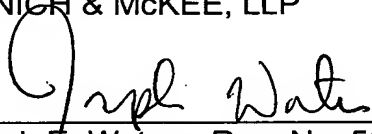
In view of the above, Appellant respectfully submits that claims 1-19 are not anticipated or rendered obvious by the cited art.

Accordingly, it is respectfully requested that the Examiner's rejections be reversed.

Respectfully submitted,

FAY, SHARPE, FAGAN
MINNICH & McKEE, LLP

Dated: Dec 21, 2006



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VIII. APPENDIX OF CLAIMS (37 C.F.R. §41.37(c)(1)(viii))

1. A method of treating diseases of the skin selected from psoriasis, neurodermatitis, shingles, aphthae, lip rhagade, stomatitis herpetica, vessels with watery liquid, and diseases of the skin and mucous membrane caused by herpes simplex virae, said method comprising the administration to the area to be treated of tosylchloramide(s), tosylchloramide salt(s), or mixtures thereof.
2. The method of Claim 1, characterized in that the diseases affect the skin and the mucous membranes.
3. The method of Claim 2, characterized in that the diseases result in efflorescences.
4. The method of Claim 2, characterized in that the diseases and/or efflorescences are caused by microorganisms and/or accompanied by microorganisms.
5. The method of Claim 1, characterized in that the diseases constitute parasitic diseases.
6. The method of Claim 1, characterized in that the diseases affect:
 - a) the lid, conjunctiva or cornea of the eye;
 - b) the exterior of the ear;
 - c) the nasal cavity;
 - d) the lips and mucous membranes of the mouth and/or the tongue;
 - e) the vulva and/or vagina;
 - f) the penis;
 - g) the anus;
 - h) the nail;
 - i) the hair follicles and/or the sebaceous glands; and/or
 - j) the hands and feet.

7. The method of Claim 1, wherein said tosylchloramide(s), and/or tosylchloramide salt(s), are present in an employed base in an amount of approximately 0.1 to 20% by weight.
8. The method of Claim 1, wherein a tosylchloramide salt is employed.
9. The method of Claim 7, wherein the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.
10. The method of Claim 9, wherein the base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension.
11. The method of Claim 9, wherein the base constitutes a dosed aerosol or a dosed solution.
12. The method of Claim 9, wherein the base constitutes a bath water additive.
13. The method of Claim 9, wherein the base is an O/W- or a W/O-emulsion ointment.
14. The method of Claim 7, wherein the base is a cortisone-containing preparation, containing the tosylchloramide(s), and/or tosylchloramide salt(s), in an amount of approximately 0.1 to 20% by weight.
15. The method of Claim 9, wherein the base is a gel comprising the tosylchloramide(s), and/or tosylchloramide salt(s), in an amount of approximately 0.1 to 5% by weight.

16. The method of Claim 9, wherein the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

17. The method of Claim 1, wherein the tosylchloramide(s), and/or tosylchloramide salt(s), are present in an employed base in an amount of approximately 5 to 15% by weight.

18. The method of Claim 1, wherein the tosylchloramide(s), and/or tosylchloramide salt(s), are present in an employed base in an amount of approximately 8 to 12% by weight.

19. The method of Claim 9, wherein the base is a gel, in which are present the tosylchloramide(s), and/or tosylchloramide salt(s), in an amount of approximately 0.1 to 2% by weight.

IX. EVIDENCE APPENDIX (37 C.F.R. §41.37(c)(1)(ix))

None.

X. RELATED PROCEEDINGS APPENDIX (37 C.F.R. §41.37(c)(1)(x))

None.